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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,593	06/27/2001	F. Mark Ferguson	SHP025.1	4461

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SPECIALIZED HEALTH PRODUCTS INTERNATIONAL INC.
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EXAMINER

SERKE, CATHERINE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,593

Applicant(s)

FERGUSON ET AL.

Examiner

Catherine Serke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,24,26,32-59,61,66-68,73-90 and 93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10-16,18-20,23,27,28,63-65,69,70,72,91 and 92 is/are rejected.
- 7) ☒ Claim(s) 3,4,8,9,17,25,29-31,60,62 and 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4,8 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of species a in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the species are so closely related that combining the, would not provide an undue burden to consider them together. This is not found persuasive because it is the policy of the office to issue one patent for one invention and not multiple patentably distinct embodiments of an invention.

The requirement is still deemed proper and is therefore made FINAL. However, claims 14, 17 and 70 have been rejoined at applicant's request since these claims contain language that is not patentably distinct from the embodiment elected. Additionally, the examiner notes applicant's request that claim 1 be indicated as generic for species a, b, c, d, h, j, k, l and m. While claim 1 reads on species a, c and f, the other figures and descriptions do not identify a monolithic needle hub including a collar. Hence, claim 1 may be generic to species a, c and f but is not considered generic or even considered generic to all of the species indicated by applicant.

Claims 21-22, 24, 26, 32-59, 61, 66-68, 73-90 and 93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the

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following is required: the terms tabs, guide surfaces and double walled needle have not been defined in the specification. Applicant is reminded that no new matter may be added to the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-2, 69, 70, 72 and 91-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Nestell (US Pat# 5,925,020).

Nestell discloses a needle point barrier that includes a monolithic needle hub including a collar and a shield having a proximal end receivable by the collar (see figure 2). The collar has an internal cavity that is configured to receive the proximal end of the shield. The shield has a plurality of hingedly connected segments (see figures). The shield is extensible between a retracted position and an extended position (see figures 3-5). The shield also has a relief portion (42) adjacent at least one hinge and configured to flex inwardly. The needle is covered in the extended position by a linear bearing (see figure 7).

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Claims 5,7,10-11,27-28,63 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Kao et al (US 6,171,284).

Kao discloses a syringe needle cover structure that includes a needle hub having a collar (3) with an interior cavity where the hub supports a needle (see figure 3). A shield is receivable within the interior cavity of the collar in an interlocking engagement (see figure 4). The shield is extensible from a retracted position to an extended position (see figures 5B-5C). The shield has at least two hingedly connected segments attached by living hinges (see figure 3) and can be locked in the extended position (3:47-55). The hinges have cut out portions shown in figure 4 to facilitate bending of the material. The needle is open ended and has a bevel. The bevel is considered to be in a plane of symmetry with any tangential plane to the circular shield.

Claims 5-6,10-16,18-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Injectimed, Inc. (WO 97/31666).

Injectimed discloses a needle tip guard for hypodermic needles that includes a monolithic needle hub with a collar (15) with an interior cavity where the hub supports a needle (see figure 23). A shield is receivable within the interior cavity of the collar in an interlocking engagement (see figure 23). The shield is extensible from a retracted position to an extended position (see figures 16-17). The shield can be irreversibly locked in the extended position by a linear bearing (see figure 31). The shield also has an articulating actuator or retention catch (see figure 23 # 26). A luer fitting (101) for attachment to a syringe is shown.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kao or Injectimed.

Kao and Injectimed meet the claim limitations as described above but fail to include a double walled needle. At the time of the invention, it would have been obvious to incorporate a double walled needle since these needles are well known in the art, the incorporation of such a needle would not materially alter the functioning of the device and the needle would improved the performance of the insertion into the patient.

Allowable Subject Matter

Claims 3-4,8-9,17,25,29-31,60,62 and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat#s 5,599,318; 5,746,726; 5,348,544; and 5,957,892 disclose analogous

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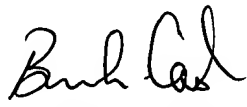
inventions in the art. US Pub #s 2003/0004465; 2002/0072716; and 2001/0039401 disclose analogous inventions in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *CS.*
February 10, 2003


BRIAN L. CASLER
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